

**Appln No. 09/308,607**  
**Amdt date July 8, 2003**  
**Reply to Office action of April 8, 2003**

**REMARKS/ARGUMENTS**

Claims 1 to 5 and 11 to 18, as amended, are pending. Applicant has amended claims 1 and 5 and added new claims 16 to 18. Support for the amendments to claims 1 and 5 can be found in the original specification at page 7, lines 11 to 18. Support for new claim 18 can be found in the original specification at page 7, lines 29 to 32. No new matter is presented. In view of the above amendments and following remarks, Applicant respectfully requests favorable reconsideration and a timely indication of allowance.

The Examiner rejected claims 1, 2, 5, 11, 14 and 15 under 35 U.S.C. § 103(a) as allegedly unpatentable over Schumacher (DE 3835728 A1) or Reetz et al. (DE 4118752 A1) in combination with Vit et al. (U.S. Patent No. 4,693,986). The Examiner rejected claims 3, 4, 12 and 13 under 35 U.S.C. § 103(a) as allegedly unpatentable over Schumacher or Reetz in combination with Vit and Urist (U.S. Patent No. 4,596,574). Applicant respectfully traverses these rejections.

Claim 1, as amended, recites a process for producing porous spherically-shaped bio-ceramics comprising dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm, followed by freeze drying and then sintering the same, wherein the starting material is obtained by adding, to a calcium phosphate in the form of a powder having a size of not more than 100  $\mu\text{m}$ , a 3 to 15% by weight aqueous solution of a binder in an amount of 2 to 4 times the weight of the powder. It has been discovered that this process results in spherical-shaped bioceramic particles having a relatively large size, for example, about 10 mm, and having a uniform porosity. The bioceramic particles produced in accordance with the invention are particularly useful for the preparation of bone filler or other biorepair material and for impregnating a drug into the pores of the particles. Independent claim 5 has been similarly amended to recite the step of

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dropping the starting material into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm.

The claimed process is neither taught nor suggested by the cited combination of references. Schmacher discloses producing particles having a size ranging from about 1 to 1000 nm by atomizing a solution containing the ceramic material in a cold reactor to freeze the droplets, followed by freeze drying and sintering. This atomizing is a spraying method, which, as discussed in the present specification at page 2, is disadvantageous for producing particles having a size of 100  $\mu\text{m}$  or more. Moreover, Schmacher's spray method is not useful for the producing of bioceramics, which must have biocompatibility, because the spray method does not necessary form a consistent product. In contrast, the present method permits the starting slurry to be dropwise discharged in a controlled manner to thereby produce spherical bioceramic particles having a uniform particle size. Schmacher nowhere teaches or suggests the claimed step of dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm.

Reets discloses a sintered ceramic spray-dried granulate in spherical form having an average size of 0.04 to 0.4 mm, which is obtained by spraying the ceramics spherical granulate into a low temperature cooling medium. As discussed above, such spraying techniques are not particularly suitable for bioceramics. Reets nowhere teaches or suggests the claimed step of dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm.

Vit discloses a method of processing sinterable powders into sintered ceramic products, preferably by spray-drying under heat. According to Vit's method, powder having a particle size of about 1 to 75  $\mu\text{m}$  is formed by the spraying method. Vit nowhere teaches or suggests the claimed step of dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm.

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Urist simply discloses a composition comprising a physiologically acceptable biodegradable porous ceramic containing bone morphogenic protein (BMP) obtained by contacting a physiologically acceptable, bioodegradable porous ceramic with a liquid containing substantially pure BMP and removing the liquid therefrom so that an effective amount of BMP is entrapped in the porous ceramic. However, Urist fails to disclose the production of spherically-shaped bioceramics having the controlled size according to the invention, much less dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm.

Accordingly, none of the references teaches or suggests the claimed step of dropping a starting material for ceramics into a low temperature medium from a thin tube having an inner diameter ranging from about 0.3 to 2 mm. Therefore, none of the references, even in combination, render unpatentable claimed invention. Applicant therefore respectfully requests that the rejections under section 103(a) be withdrawn.

In view of the foregoing amendments and remarks, Applicant respectfully submits that pending claims are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,

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626/795-9900

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EDB PAS513726.1-\*07/8/03 9:46 AM